Summary of Safety and Effectiveness
Liquichek Hematology Control (A)

1.0 **Submitter**

JUN 2 8 2004

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Contact Person

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Date of Summary Preparation

May 28, 2004

2.0 **Device Identification**

Product Trade Name:	Liquichek Hematology Control (A)
Common Name:	Hematology and Pathology Devices (Hematology quality control mixture)
Classifications:	Class II
Product Code:	JPK
Regulation Number:	21 CFR 864.8625

3.0 **Device to Which Substantial Equivalence is Claimed**

Tri-Count 20 Hematology Whole Blood Control
Bio-Rad Laboratories (formerly known as Hematronix, Inc.)
Plano, Texas 75074

510 (k) Number: K960471

4.0 **Description of Device**

Liquichek Hematology Control (A) is a suspension of stabilized human white cells, simulated human platelets of animal origin, and lysable human red cells. This product contains soluble stabilizers and preservatives to maintain the stability of the cellular components. This product is provided in liquid form.

5.0 **Intended Use**

Liquichek Hematology Control (A) is an assayed whole blood control for evaluating precision of hematology instruments that provide a white blood cell differential.

6.0 Comparison of the new device with the Predicate Device

Liquichek Hematology Control (A) claims substantial equivalence to the Tri-Count 20 Hematology Whole Blood Control currently in commercial distribution (K960471).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Liquichek™ Hematology Control (A) (New Device)	Bio-Rad Laboratories (formerly known as Hematronix, Inc.) Tri-Count 20 Hematology Whole Blood Control (Predicate Device K942295)
Similarities		
Intended Use	Liquichek Hematology Control (A) is an assayed whole blood control for evaluating precision of hematology instruments that provide a white blood cell differential	TRI-COUNT 20 is a hematology reference control used in monitoring determination of blood cell values on COULTER STKS, MAXM and other analyzers.
Form	Liquid	Liquid
Matrix	Human Whole Blood based	Human Whole Blood based
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Differences		
Open Vial Claim	7 days at 2 to 8°C	14 days at 2°C to 8°C
Analytes	Contain the following parameters same as the predicate: BASO (Basophils) EOS (Eosinophils) HCT (Hematocrit) HGB (Hemoglobin) LYMPH (Lymphocytes) MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) MCV (Mean Corpuscular Volume) MID/MONO (Monocytes Mid-Sized Cells) MPV (Mean Platelet Volume) NEU (Neutrophils) PLT (Platelets) RBC (Red Blood Cells) RDW (Red Blood Cell Distribution Width) GRAN (Granulocytes) Does not contain the following parameters: • PDW (Platelet Distribution Width) • PCT (Plateletcrit)	Contain the following parameters: BASO (Basophils) EOS (Eosinophils) HCT (Hematocrit) HGB (Hemoglobin) LYMPH (Lymphocytes) MCH (Mean Corpuscular Hemoglobin) MCHC (Mean Corpuscular Hemoglobin Concentration) MCV (Mean Corpuscular Volume) MONO (Monocytes) MPV (Mean Platelet Volume) NEUT (Neutrophils) PLT (Platelets) RBC (Red Blood Cells) RDW (Red Blood Cell Distribution Width) PDW (Platelet Distribution Width) PCT (Plateletcrit) Does not contain the following parameters: GRAN (Granulocytes) MID (Mid-Sized Cells)

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Hematology Control (A). Product claims are as follows:

7.1 Open vial: All analytes will be stable for 7 days when stored at 2 to 8°C.
7.2 Shelf Life: 60 days at 2 to 8°C.
All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 8 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/ Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: k041457
Trade/Device Name: Hematology Control
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: Class II
Product Code: JPK
Dated: May 28, 2004
Received: June 1, 2004

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041457

Device Name: **Liquichek Hematology Control (A)**

Indications For Use: **Liquichek Hematology Control (A) is an assayed whole blood control for evaluating precision of hematology instruments that provide a white blood cell differential.**

The following parameters are listed in the package insert:

- BASO (Basophils)
- EOS (Eosinophils)
- GRAN (Granulocytes)
- HGB (Hemoglobin)
- HCT (Hematocrit)
- LYMPH (Lymphocytes)
- MPV (Mean Platelet Volume)
- MCV (Mean Corpuscular Volume)
- MCHC (Mean Corpuscular Hemoglobin Concentration)
- MCH (Mean Corpuscular Hemoglobin)
- MONO/MID (Monocytes/Mid-Sized Cells)
- NEU (Neutrophils)
- PLT (Platelets)
- RDW (Red Cell Distribution Width)
- RBC (Red Blood Cells)
- WBC (White Blood Cells)
  - NOC (Nucleated Optical Count)
  - WIC (White Impedance Count)
  - WOC (White Optical Count)

Performance claims were established using the Abbott Cell-Dyn 3000.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041457